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A PILOT STUDY OF PATIENT PREFERENCES FOR MID-THERAPY ASSESSMENT TIMING IN CHRONIC HEPATITIS C TREATMENT

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OBJECTIVES: For many courses of therapy, assessments of treatment effectiveness are used to inform treatment continuation decisions. If a "mid-therapy" assessment (MTA) is positive, the patient is indicated to continue treatment; if negative, treatment may be discontinued. Using expected utility theory, we demonstrated previously that the availability and timing of such assessments may influence patients' treatment initiation decisions. We conducted a pilot study among chronic hepatitis C (CHC) patients to examine preferences over MTA timing and treatment initiation. **METHODS:** A stated preference survey was developed and pre-tested among 10 community volunteers and then administered to 49 CHC patients. The survey described two MTAs for CHC treatment: one at 4 weeks (rapid virologic response, RVR) and the other at 12 weeks (early virologic response, EVR). Test characteristics varied between the two MTAs, but the decision algorithm (stated above) was held constant. Multiple response formats were used to elicit preferences across MTA and treatment initiation. Results are summarized as means and proportions. **RESULTS:** Average age was 54.6 yrs; 55.1% were male; 32.7% were treatment-naïve; 67.3% reported their general health as good or better. Three subjects failed to answer one or more MTA or treatment choice questions. More subjects had previously heard of EVR compared to RVR (43.8% vs. 14.3%, $p > 0.01$). Given a choice between MTAs, 55.3% of subjects indicated a preference for RVR. Treatment utilizing RVR was somewhat or strongly preferred by 57.4% of subjects, and 61.2% said they would choose RVR if only one test was available. However, more subjects responded that they would accept treatment with EVR than with RVR 60.9% vs. 55.3% (difference not significant). **CONCLUSIONS:** Patients with CHC consistently indicated MTA preferences that are at odds with current treatment guidelines. Further research is needed to understand the relationship between MTA preference and treatment initiation.

PGI25

CHILD AND PARENT REPORTS OF SYMPTOMS OF IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C): RESULTS OF QUALITATIVE INTERVIEWS

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OBJECTIVES: The Rome III criteria define pediatric irritable bowel syndrome with constipation (IBS-C) as abdominal pain or discomfort associated with constipation symptoms. Historically, few pediatric IBS-C trials have used symptom measures that were developed with patient input. This study aimed to develop pediatric IBS-C symptom measures through qualitative interviews with children with IBS-C and their parents/caregivers. **METHODS:** Children diagnosed with IBS-C (aged 6–8 [n = 10], 9–11 [n = 10] and 12–17 [n = 10]) and their parents were interviewed. Thematic analysis of interview transcripts identified concepts. Age appropriate items and response options, developed to measure each concept, were reviewed by expert clinicians. **RESULTS:** IBS-C symptoms identified as being bothersome to children included: abdominal symptoms such as abdominal pain ("stomach hurts") and bloating ("tummy like a balloon"), and bowel symptoms such as infrequent bowel movements ("don't go often"), difficulty defecating ("it won't come out"), straining on defecation ("have to push hard"), rectal pain during defecation ("butt hurts"), hard stools ("hard and bumpy"), large stools ("it's like a log"), and a feeling of incomplete evacuation ("some that won't come out"). Saturation was achieved for the above concepts. Parents relied on behavioural signs of IBS-C (such as inactivity or irritability) and the child telling them about symptoms when assessing their child's condition. In general the majority of parents and children agreed in their reports of symptoms, though there were some minor inconsistencies. **CONCLUSIONS:** Consistent with guidelines for patient-reported outcomes, these results were used to develop age-appropriate questions to measure both abdominal and bowel symptoms. The instrument is currently undergoing testing to assess patient understanding and relevance. Results from qualitative interviews with children with IBS-C suggest abdominal and bowel symptoms are both important and bothersome to pediatric IBS-C patients and should be included in treatment assessments.

PGI26

PREVALENCE AND IMPACT IN WORK PRODUCTIVITY OF GASTRO-ESOFAGEAL REFLUX DISEASE (GERD) IN PRIMARY CARE PATIENTS WITH UPPER GASTROINTESTINAL (GI) SYMPTOMS. THE GREEK GERDQ STUDY

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OBJECTIVES: GERD is a common condition in daily clinical practice associated with reduced quality of life and impact on productivity. The aims of the current study were to estimate the prevalence of GERD in primary care by using a novel diagnostic tool (GerdQ questionnaire) and to assess the impact of the disease in productivity. **METHODS:** The Greek GerdQ study was a cross-sectional, single-visit, epidemiological study in patients presenting to their physician with upper GI symptoms. Data on patients' demographics, medical/GI history and upper GI symptoms were recorded by the investigators. All subjects completed the GerdQ, and those scored ≥ 8 also completed the WPAI-GERD questionnaire for the evaluation of GERD impact on productivity. **RESULTS:** Overall 889 (887 evaluable) patients were enrolled by 91 primary care physicians. 47% of patients were male. Mean (± SD) age was 51 (17) years with 37.5% of patients presenting no previous history of GI tract disorders. The most prevalent GI symptoms in the week prior to study visit were heartburn, regurgitation and belching, presenting a high frequency (≥2 days/week or daily) in 62.4%, 47% and 50.2% of the patients, respectively. Antisecretory treatment was reported by 62% of patients. Based on GerdQ, 71.8% patients had GERD (GerdQ score ≥ 8) while 45.1% of them were suffering from disrupting disease (GerdQ impact score ≥ 3). Mean (± SD) absenteeism due to GERD was 2.3 (4.9) hours/week with a mean (± SD) of 11.8 (9.6) additional hours/week lost due to presenteeism. The observed reduction in daily life productivity was 37.4%. **CONCLUSIONS:** These data suggest that in Greece, GERD is a highly prevalent condition in primary care patients with upper GI symptoms, posing a significant burden to patients in terms of reduced productivity both in work and in daily life.

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STRUCTURED MANAGEMENT STRATEGY BASED ON THE GERDQ QUESTIONNAIRE VERSUS USUAL PRIMARY CARE FOR GASTROESOPHAGEAL REFLUX DISEASE: META-ANALYSIS OF FIVE EUROPEAN CLUSTER RANDOMIZED TRIALS

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OBJECTIVES: Gastroesophageal reflux disease (GERD) has substantial impact in primary care, but the optimal approach to management is uncertain. a structured management strategy may improve the diagnosis and therapeutic management of GERD, but individual studies may be limited by their focus on local strategies that may not be valid for other countries. **METHODS:** We conducted a meta-analysis of five cluster randomised clinical trials comparing a new management strategy with usual care in patients with GERD conducted in Austria, Italy, Norway, Spain and Sweden (NCT00842387). The intervention strategy was based on the self-administered validated GerdQ questionnaire to stratify adult patients with classical symptoms of GERD (heartburn or regurgitation) according to the frequency and impact of symptoms. The most effective acid-suppressive therapy (esomeprazole 40 mg once daily) was used only in patients with the highest GerdQ symptom impact score (≥3). The primary outcome was non-response to treatment defined as a total GerdQ score ≥ 8 at the end of follow-up. Odds ratios for the primary outcome were combined using a random effects model. **RESULTS:** A total of 2400 patients were enrolled and average follow-up ranged from 4 to 18 weeks. The odds ratios for lack of treatment response with the structured management strategy compared with usual care ranged from 0.22 to 0.84, across studies. The random-effects combined odds ratio for non-response to treatment was 0.56 (95% CI 0.22–0.90; $p = 0.001$), with significant between-study heterogeneity ($p < 0.001$). **CONCLUSIONS:** Stratification of patients according to the GerdQ questionnaire, using a locally adapted primary care management strategy for GERD significantly increased the likelihood of a response to treatment compared to usual clinical practice, although significant between-country heterogeneity suggests that GERD management can still be improved.

PGI28

HEALTH-RELATED QUALITY OF LIFE IN OPIOID INDUCED CONSTIPATION PATIENTS IN SPAIN

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OBJECTIVES: To analyze the impact of opioid induced constipation (OIC) on patients' health related quality of life (HRQoL). **METHODS:** An observational, multicenter study was carried out in Spain. All patients were free of constipation at baseline and received opioids for at least 2 months. The impact of OIC on patients' HRQoL was determined in a cross-sectional phase of the study. Patients were evaluated depending on response to oral treatment for OIC. HRQoL was assessed by the following tools: the Spanish version of the EuroQoL (EQ-5D) and EuroQoL Visual Analogue Scale (EQ-VAS). The CVE-20 questionnaire and a specific question were used to assess the perceived health status related to constipation. **RESULTS:** Patients with OIC showed a mean (SD) overall CVE-20 score of 48.0 (18.6), the time spent defecating and discomfort caused by a bloated stomach were highly rated in the general physical dimension (56.4% in both items). Laxative dependence was the most rated item (51.9%) in the social dimension. Regarding general QoL, EQ-5D, the dimension in which patients were more affected was the pain/discomfort dimension (89.7%). Mean EQ-VAS score (SD) was 51.3 (19.3), mean EQ-5D VAS tariff (SD) was 0.45 (0.25) and mean EQ-5D TE tariff (SD) was 0.38 (0.40). Overall, responders to oral laxatives showed a better HRQoL than non-responders. The CVE-20 questionnaire score in responders was higher than in non-responders (50.8 vs. 40.6, respectively, $P < 0.001$). Regarding general QoL, the EQ-5D anxiety/depression was the only dimension significantly more affected in non-responders ($p = 0.003$). Accordingly, responders obtained statistically significant higher EQ-VAS score (SD), 53.0 (18.9) vs. 45.5 (18.4) ($p = 0.004$). **CONCLUSIONS:** OIC is one of the most distressing opioid adverse events and as such, has a negative impact on HRQoL. The differences observed in the CVE-20 and EQ-VAS scores between responders and non-responders are statistically significant and may also have a clinical impact.